Application No. 10/549,760 Reply to Final Action Attorney Docket No. 104072.B870248

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A composite microsphere system comprising consisting essentially of

poly(D,L-lactide-co-glycolide) (PLGA); poly(acryloyl hydroxyethyl starch) (AcHES); and

a pharmaceutically effective amount of a biologically active compound; wherein the biologically active compound is a polypeptide having a molecular weight of about 200 to about 160,000 Daltons, and wherein the biologically active compound is selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an erythropoietin (EPO), an epidermal growth factor (EGF) and a growth hormone.

2. (canceled)

3. (withdrawn) A drug formulation comprising a composite microsphere system comprising

poly(D,L-lactide-co-glycolide) (PLGA); poly(acryloyl hydroxyethyl starch) (AcHES); and

a pharmaceutically effective amount of a biologically active compound;

wherein the biologically active compound is selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an

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erythropoietin (EPO), an epidermal growth factor (EGF) or a growth hormone; and

a pharmaceutically acceptable vehicle.

4. (withdrawn) A method for the sustained release delivery of a therapeutic compound to a subject comprising:

administering to the subject a composite microsphere system comprising poly(D,L-lactide-co-glycolide) (PLGA);

poly(acryloyl hydroxyethyl starch) (AcHES); and

a pharmaceutically effective amount of a biologically active compound;

wherein the biologically active compound is selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an erythropoietin (EPO), an epidermal growth factor (EGF) or a growth hormone.

- 5. (withdrawn) The method of claim 4, wherein the subject is suffering from a condition which can be treated by the administration of a biologically active compound selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an erythropoietin (EPO), an epidermal growth factor (EGF) or a growth hormone.
- 6. (withdrawn) The method of claim 4, wherein the subject is a vertebrate or an invertebrate organism.

- 7. (withdrawn) The method of claim 4, wherein the subject is a canine, a feline, an ovine, a primate, an equine, a porcine, a caprine, a camelid, an avian, a bovine, an amphibian, a fish, or a murine organism.
- 8. (withdrawn) The method of claim 4, wherein the primate is a human.
- 9. (withdrawn) The method according to claim 4, wherein the drug is administered intramuscularly.
- 10. (withdrawn) The method of claim 4, wherein the microspheres are in a pharmaceutically acceptable vehicle.
- 11. (withdrawn) The method of claim 4, wherein the microspheres are administered topically.
- 12. (withdrawn) The method of claim 11, wherein the topical administration is via inhalation or nasal administration.
- 13. (withdrawn) The method of claim 4, wherein the microspheres are administered parenterally.
- 14. (withdrawn) A method of preparing a composite microsphere system of claim 2, comprising

incorporating a biologically active ingredient selected from the group consisting of an insulin, an interferon, a luteinizing hormone-releasing hormone (LHRH) analog, a somatostatin and/or somatostatin derivative, a calicitonin, a parathyroid hormone (PTH), a bone morphogenic protein (BMP), an erythropoietin (EPO), an epidermal growth factor (EGF) or a growth hormone into AcHES hydrogel microparticles; and

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encapsulating the resulting AcHES hydrogel microparticles containing the biologically active ingredient into a PLGA matrix.

15. (withdrawn) The method of claim 14, wherein the AcHES hydrogel microparticles containing the biologically active ingredient are incorporated into the PLGA matrix using a process selected from the group consisting of solvent extraction, solvent evaporation, spray drying, freeze drying and a combination thereof.